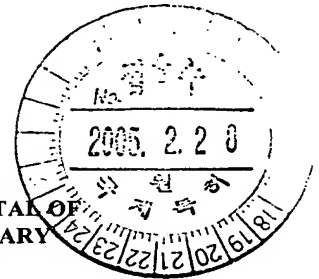


PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING

PCT



To:

LEE, Won-Hee

8th Fl., Sung-ji Heights II, 642-16, Yoksam-dong, Kangnam
-Ku, Seoul 135-080, Republic of KOREA

NOTIFICATION OF TRANSMITTAL OF
INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing
(day/month/year) 25 FEBRUARY 2005 (25.02.2005)

Applicant's or agent's file reference
2FPO-09-28

IMPORTANT NOTIFICATION

International application No.

PCT/KR2002/001837

International filing date (day/month/year)

30 SEPTEMBER 2002 (30.09.2002)

Priority date (day/months/year)

Applicant

REGEN BIOTECH, INC. et al

1. The applicant is hereby notified that International Preliminary Examining Authority transmits here with the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.


4. REMINDER

The applicant must enter the national phase before each elected office by performing certain acts (filing translations and paying national fees) within 30 month(s) from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details in the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/KR

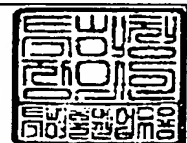
 Korean Intellectual Property Office
920 Dunsan-dong, Seo-gu, Daejeon 302-701,
Republic of Korea

Facsimile No. 82-42-472-7140

Authorized officer

COMMISSIONER

Telephone No. 82-42-481-5281

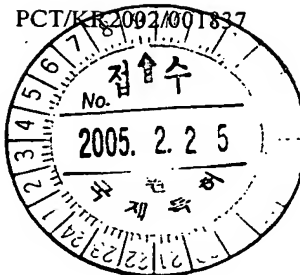


PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference 2FPO-09-28	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/KR2002/001837	International filing date (day/month/year) 30 SEPTEMBER 2002 (30.09.2002)	Priority date (day/month/year)
International Patent Classification (IPC) or national classification and IPC IPC7 A61L 27/14		
Applicant REGEN BIOTECH, INC. et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 3 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 04 MARCH 2004 (04.03.2004)	Date of completion of this report 23 FEBRUARY 2005 (23.02.2005)
Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer KIM, Seung Soo Telephone No. 82-42-481-5581 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/KR2002/001837

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement) under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language English which is

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☒ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION

International application No.

PCT/KR2002/001837

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	1-10	YES
	Claims		NO
Inventive step (IS)	Claims	1-10	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-10	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following documents:

D1) US 6344488 B1

D2) Biomaterials, Vol.20:1603-1612

D3) International Journal of Pharmaceutics, Vol.233:217-225

D4) J Clin Invest, Vol.110:751-759

D5) Bone, Vol.31:340-347

I—Novelty:

Claim 1 of the present invention is concerned with a composition containing tripolyphosphate and water-soluble chitosan for stimulating bone-formation and bone-consolidation. Although D1 cited in the international search report discloses chitosan/organo-phosphate aqueous systems, tripolyphosphate/chitosan systems are not described in D1. And also, D2-D4 cited in the international search report do not refer to the use of water-soluble chitosan. Accordingly, the subject matter of claim 1 seems to be novel.(PCT Article 33(2)). Claims 2-10 also comply with PCT Article 33(2) as they are dependent claims.

II—Inventive step:**1) Concerning claim 1 (Independent claim)**

The references D1-D5 do not disclose the combination of tripolyphosphate and water-soluble chitosan for stimulating bone-formation and bone consolidation. In addition, it is not obvious from the references D1-D5 by the skilled person in the art. Consequently, there is no suggestion in any of the references, either alone or in combination, which would lead to the solution posed by the present invention. Therefore, claim 1 of the present invention meets the criteria set out in PCT Article 33(3).

2) Concerning claims 2 to 10 (dependent claims)

claims 2-10 also comply with PCT Article 33(3) as they are dependent claims.